



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/889,106 | 07/11/2001 | Haile Tecle | 5940-01-SMH | 7962 |

7590 09/30/2002
Evelyn D Shen
Legal Division
Warner Lambert Company
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER

SHAMEEM, GOLAM M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

DATE MAILED: 09/30/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,106

Applicant(s)

TECLE ET AL.

Examiner

Golam M M Shameem

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-50, are pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. W, R₁, R₄ and R₅ etc. (and the provisos) and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I claim(s) 1-29, drawn to a compound of the formula (I) wherein, R₁ is heterocyclic radical (such as pyrrole, pyrazole), R₂ and R₃ is independently H, phenyl, C₁₋₄ alkyl, C₃₋₈ alkynyl, C₃₋₈ cycloalkyl, R₄, R₅ and R₆ is independently H, Cl, F, or Br, R_A and J are heterocyclic radical (such as pyrrole, pyrazole), R_C, R_D, R_E, R_F and R_G is independently selected from pyrrolidinyl and all other variable substitutions are as defined and one method of use (e.g. treating cancer).

Group II claim(s) Group I claim(s) 1-29, drawn to a compound of the formula (I) wherein, R₁ is heterocyclic radical (such as morpholinyl, pyrazinyl), R₂ and R₃ is independently H, phenyl, C₁₋₄ alkyl, C₃₋₈ alkynyl, C₃₋₈ cycloalkyl, R₄, R₅ and R₆ is independently H, Cl, F, or Br, R_A and J are heterocyclic radical (such as morpholinyl, pyrazinyl), R_C, R_D, R_E, R_F and R_G is independently selected from pyrazinyl and all other variable substitutions are as defined and one method of use (e.g. treating septic shock).

Art Unit: 1626

Group III Group I claim(s) 1-29, drawn to a compound of the formula (I) wherein, R_1 is non-heterocyclic radical (such as H, C_{1-8} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8} cycloalkyl etc.), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are non-heterocyclic radical (such as H, C_{1-6} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8} cycloalkyl etc.), R_C , R_D , R_E , R_F and R_G is independently selected from non-heterocyclic radical (such as H, C_{1-6} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8} cycloalkyl etc.) and all other variable substitutions are as defined and one method of use (e.g. treating cystic fibrosis).

Group IV claims 30-48, drawn to a method for treating a disease with the compound of the formula (I) wherein, R_1 is heterocyclic radical (such as pyrrole, pyrazole), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are heterocyclic radical (such as pyrrole, pyrazole), R_C , R_D , R_E , R_F and R_G is independently selected from pyrrolidinyl and all other variable substitutions are as defined heterocyclic radical and all other variable substitutions are as defined.

Group V claims 30-48, drawn to a method for treating a disease with the compound of the formula (I) wherein, R_1 is heterocyclic radical (such as morpholinyl, pyrazinyl), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are heterocyclic radical (such as morpholinyl, pyrazinyl), R_C , R_D , R_E , R_F and R_G is independently selected from pyrazinyl and all other variable substitutions are as defined.

Group VI Group I claim(s) 30-48, drawn to a compound of the formula (I) wherein, R_1 is non-heterocyclic radical (such as H, C_{1-8} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8}

Art Unit: 1626

cycloalkyl etc.), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are non-heterocyclic radical (such as H, C_{1-6} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8} cycloalkyl etc.), R_C , R_D , R_E , R_F and R_G is independently selected from non-heterocyclic radical (such as H, C_{1-6} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8} cycloalkyl etc.) and all other variable substitutions are as defined.

Group VII claims 49-50, drawn to a method for treating a disease with chemotherapy using the compound of the formula (I) wherein, R_1 is heterocyclic radical (such as pyrrole, pyrazole), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are heterocyclic radical (such as pyrrole, pyrazole), R_C , R_D , R_E , R_F and R_G is independently selected from pyrrolidinyl and all other variable substitutions are as defined.

Group VIII claims 49-50, drawn to a method for treating a disease with chemotherapy using the compound of the formula (I) wherein, R_1 is heterocyclic radical (such as morpholinyl, pyrazinyl), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are heterocyclic radical (such as morpholinyl, pyrazinyl), R_C , R_D , R_E , R_F and R_G is independently selected from pyrazinyl and all other variable substitutions are as defined.

Group IX claims 49-50, drawn to a method for treating a disease with chemotherapy using the compound of the formula (I) wherein, R_1 is non-heterocyclic radical (such as H, C_{1-8} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C_{3-8} cycloalkyl etc.), R_2 and R_3 is independently H, phenyl, C_{1-4} alkyl, C_{3-8} alkynyl, C_{3-8} cycloalkyl, R_4 , R_5 and R_6 is independently H, CL, F, or Br, R_A and J are non-heterocyclic radical (such as H, C_{1-6} alyl, C_{3-8} alkenyl, C_{3-8} alkynyl, phenyl, C

Art Unit: 1626

₃₋₈ cycloalkyl etc.), R_C, R_D, R_E, R_F and R_G is independently selected from non-heterocyclic radical (such as H, C₁₋₆ alyl, C₃₋₈ alkenyl, C₃₋₈ alkynyl, phenyl, C₃₋₈ cycloalkyl etc.) and all other variable substitutions are as defined.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same. If applicant wishes to elect subject matter other than that identified in the above groups, applicant may elect a species and examiner will attempt to group it. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a heterocyclic or non-heterocyclic radical substitution, which is attached to core benzene ring that does not define a contribution over the prior art. The substituents on the benzene ring vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, the numerous provisos found in the claims, and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

Conclusion

Art Unit: 1626


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is 703-305-0116. The examiner can normally be reached on 6:30 AM to 5:00 PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 703-308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for after final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A facsimile center has been established. The hours of operation are Monday through 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1


Joseph K McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1

September 26, 2002